

2



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,196	01/22/2001	Ronald J. Lebel	047711-0221	1919

23709 7590 07/09/2002

MEDICAL RESEARCH GROUP INC
ATTN DENNIS SMALLEY
12744 SAN FERNANDO ROAD
BLDG 4
SYLMAR, CA 91342

EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
----------	--------------

3763

DATE MAILED: 07/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/768,196

Applicant(s)

LEBEL ET AL. *Ch*

Examiner

Matthew F DeSanto

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 6) ☐ Other: _____

Art Unit: 3763

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1, 2, 3, 5, 6, 7, 8, 10, 12, 13, 14, and 16 are rejected under 35 U.S.C 102(b) as being anticipated by Tune et al. (USPN 5630710). Tune et al. discloses a medical system, comprising an ambulatory medical device (MD) comprising MD electronic control circuitry (546) that further comprises at least one MD telemetry system (562, 564, 566) and at least one MD processor (542) that controls, at least in part, operation of the MD telemetry system and operation of the medical device, wherein the medical device is configured to provide a treatment to a body of a patient or to monitor a selected state of the body; and b) a communication device (CD) comprising CD electronic control circuitry that further comprises at least one CD telemetry system and at least one CD processor that controls, at least in part, operation of the CD telemetry system and operation of the communication device, wherein the CD telemetry system sends messages to or receives messages from the MD telemetry system, wherein the medical device is comprises an infusion pump (10), and wherein the CD display device is controlled to show a

Art Unit: 3763

plurality of infusion parameters simultaneously, and wherein a first portion of the MD telemetry system is incorporated into the MD processor and a second portion of the MD telemetry system is external to the MD processor, or wherein a first portion of the CD telemetry system is incorporated into the CD processor and a second portion of the CD telemetry system is external to the CD processor, wherein (1) the MD electronic control circuitry comprises at least one external MD functional module, other than the second portion of the MD telemetry system, that is external to the MD processor, (2) the CD electronic control circuitry comprises at least one external CD functional module, other than the second portion of the CD telemetry system, that is external to the CD processor, (3) the MD processor comprises an internal MD CPU and at least one other internal MD functional module, or (4) the CD processor comprises an internal CD CPU and at least one other internal CD functional module. (Figures 2,25-30,32-41, and entire reference).

Tune et al. also discloses the communication device with a CD display controlled by at least one CD processor (576) for providing visual feedback to the patient, and wherein the feedback comprises a display of the quantity of a consumable estimated to be remaining in the system (512), wherein the consumable is a drug, and where the medical device wherein infusion parameters can be selected, and where the patient can program (28) there own options into the pump. (Column 3, lines 29-47).

3. Claims 12 and 15 rejected under 35 U.S.C. 102(b) as being anticipated by Snell et al. (USPN 5759199). Snell discloses a medical system, comprising an ambulatory medical device (MD) comprising MD electronic control circuitry that further comprises at least one MD telemetry system and at least one MD processor that controls, at least in part, operation of the

Art Unit: 3763

MD telemetry system and operation of the medical device, wherein the medical device is configured to provide a treatment to a body of a patient or to monitor a selected state of the body; and b) a communication device (CD) comprising CD electronic control circuitry that further comprises at least one CD telemetry system and at least one CD processor that controls, at least in part, operation of the CD telemetry system and operation of the communication device, wherein the CD telemetry system sends messages to or receives messages from the MD telemetry system and wherein there is a CD display that depicts a plurality of patient programmable options, and where the medical device is implantable. (Page 6, line 64 - page 7, line 29; pg 7, line 62-67, pg 8, line 22- 31, and lines 55-58, and entire reference).

4. Claims 1, 4, 6, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Hartlaub et al. (USPN 2001/0037083). Hartlaub discloses an implantable drug infusion pump with an MD electrical circuit, a processor and a telemetry system, and a communication device, with a CD circuit, a processor and a telemetry system, and where there is a display, that displays feedback on the amount of drugs dosage remaining. (Paragraphs [009], [0010], [0011], [0021], [0023], [0027] and [0038] and the entire reference).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3763

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tune et al. as applied to claims 1-10 and 12-16 above, and further in view of Er (USPN 6185461).

8. Tune et al. discloses everything as mention above in paragraphs 2, of the claimed invention but fails to disclose wherein the consumable is either (1) battery power remained in a replaceable CD battery in the communication device and a voltage level on the CD battery is graphically depicted with a desired resolution, or (2) battery power remaining in an MD battery in the medical device and a voltage level on the battery is graphically depicted with a desired resolution.

9. Er discloses a controlled system where the display, displays the battery data and battery longevity estimate graph. (Figure 1 and 2 and entire reference).

10. At the time of the invention, it would have been obvious for a person with ordinary skill in the art to combine Tune et al. medical infusion device with Er replacement time indicator device and display, because according to Er, it is highly desirable to predict when a battery will failure so as to make arrangements for the replacement battery. (Column 2, lines 1-9).

Art Unit: 3763

Double Patenting

Claims 1-16 of this application conflict with the claims of Application Numbers 09/768044, 09/768193, 09/768194, 09/768197, 09/768198, 09/768199, 09/768204, 09/768208, and 09/768210, and 09/768221. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 1-16 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all the claims of copending Application No. 09/768044, 09/768193, 09/768194, 09/768197, 09/768198, 09/768199, 09/768204, 09/768208, and 09/768210, and 09/768221. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application all comprises of a CD, MD, a MD telemetry system, a CD telemetry system, a CD electronic control circuit, a MD electronic control circuit, a CD functional module, a MD functional module, a MD processor and a CD processor.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending

Art Unit: 3763

application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.

Matthew F DeSanto

7/1/02

MATTHEW DeSanto

[Signature]

ANH TUAN T. NGUYEN
PRIMARY EXAMINER

7/1/02